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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,861	12/26/2001	Hai Xing Chen	99,003.1	4882

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EXAMINER	
SIEW, JEFFREY	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/035,861	CHEN, HAI XING	
	Examiner	Art Unit	
	Jeffrey Siew	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *26-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,14-18* is/are rejected.

7)☒ Claim(s) *10-13 and 19-25* is/are objected to.

8)☐ Claim(s) *1-29* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in Paper filed 11/12/03 is acknowledged.

Claims 26-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper filed 11/12/03.

Pending claims to be examined are 1-25.

Priority

2. It is noted that this application appears to claim subject matter disclosed in prior copending Application No. 09/326297 , and filed June 4, 1999. A reference to the prior application must be inserted as the first sentence of the specification of this application if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). **The current status of all nonprovisional parent applications referenced should be included.**

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,2,6,14,15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5,6 of U.S. Patent No. 6,174,733. The conflicting claims are not identical, they are not patentably distinct from each other.

Claims 1,2,6,14 & 15 are drawn to method of detecting multiple test materials using a **first probe with chemical label** and detecting signals generated by labels. Claim 2 is further drawn to a triggering solution to react with labels. Claim 6 is further drawn to DNA. Claims 14 & 15 similarly are drawn to the detection of detecting multiple nucleic acid fragments using a **triggering solution** to trigger labels.

Claims 5 & 6 of US6,174,733 are drawn to method of detecting two DNA materials using **detectable label on DNA probe** and **substrate** to react with labels.

Claims 5 & 6 of US6,174,733 are drawn to a species of the generic claims 1,2,6,14 & 15 of the instant application. The species renders the genus claims obvious.

4. Claims 3-5,16 & 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5,6 of U.S. Patent No. 6,174,733 in view of Lee et al (US5,672,475 Sep. 30, 1997).

Claims 3-5,16 & 17 are drawn to method of detecting multiple analytes using chemiluminescent dye particularly acridinium dye.

Claims 5 & 6 of US6,174,733 are drawn to method of detecting two DNA materials using **detectable label on DNA probe** and **substrate** to react with labels.

Claims 5 & 6 of US6,174,733 are not drawn to acridinium dye.

Lee et al teach acridinium dye for detection (see col.2 line 25 & col. 7 line 18).

One of ordinary skill in the art would have been motivated to apply Lee et al's acridinium dye to the claims 5 & 6 of US6,174,733 in order to provide for radioactive free and highly sensitive detection label. It would have been prima facie obvious to apply Lee et al's acridinium dyes to the method claims 5 & 6 of US6,174,733 in order to increase sensitivity of detection.

5. Claims 1,2,6,14 & 15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14,15-22 of U.S. Patent No. 6,337,214. The conflicting claims are not identical, they are not patentably distinct from each other.

Claims 1,2,6,14 & 15 are drawn to method of detecting multiple test materials using a **first probe with chemical label** and detecting signals generated by labels. Claim 2 is further drawn to a triggering solution to react with labels. Claim 6 is further drawn to DNA. Claims 14 & 15 similarly are drawn to the detection of detecting multiple nucleic acid fragments using a **triggering solution** to trigger labels.

Claims 14,15-22 of US 6,337,214 are drawn to detecting the presence of DNA sequence using **labeled DNA probes** and adding **substrate to react with labels to detect**.

Claims 14,15-22 of US6,337,214 are drawn to a species of the generic claims 1,2,6,14 & 15 of the instant application. The species renders the genus claims obvious.

6. Claims 3-5,16 & 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14,15-22 of U.S. Patent No. 6,337,214 in view of Lee et al (US5,672,475 Sep. 30, 1997).

Claims 3-5,16 & 17 are drawn to method of detecting multiple analytes further using chemiluminescent dye particularly acridinium dye.

Claims 14,15-22 of US 6,337,214 are drawn to detecting the presence of DNA sequence using **labeled DNA probes** and adding **substrate to react with labels to detect**.

Claims 14,15-22 of US 6,337,214 are not drawn to acridinium dye.

Lee et al teach acridinium dye for detection (see col.2 line 25 & col. 7 line 18).

One of ordinary skill in the art would have been motivated to apply Lee et al's acridinium dye to the method claims 14,15-22 of US 6,337,214 in order to provide for radioactive free and highly sensitive detection label. It would have been prima facie obvious to apply Lee et al's acridinium dyes to the method claims 14,15-22 of US 6,337,214 in order to increase sensitivity of detection.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,2,6,7-9,14,15,18 are rejected under 35 U.S.C. 102(e) as being anticipated by Muller et al (US5,804,384 Sept. 8, 1998).

Muller et al teach a method of detecting multiple test materials in test sample by adding to a test sample to test column which has snare with two target capture materials, first target capture material being specific to a first test material , second target material being specific to second test material, washing , adding first probe with chemical label, washing, detecting and adding second probe with second probe ,washing and detecting.(see whole doc. esp. col. 1 line 56, col. 5 line 23-38,col. 9 line 5-45 & esp. col. 11 lines 21-30 & 60-65). They teach using enzyme substrate detection reagents (see col.11 line 60-65).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3-5, 16 & 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller et al (US5,804,384 Sept. 8, 1998) in view of Lee et al (US5,672,475 Sep. 30, 1997).

The teachings of Muller et al are described previously.

Muller et al do not teach acridinium dye.

Lee et al teach acridinium dye for detection (see col.2 line 25 & col. 7 line 18).

One of ordinary skill in the art would have been motivated to apply Lee et al's acridinium dye to the Muller et al's detection probe in order to provide for highly sensitive detection label. It would have been prima facie obvious to apply Lee et al's acridinium dyes to the Muller et al's detection method in order to increase sensitivity of detection.

SUMMARY

9. Claims 10-13,19-23,24 & 25 are objected for depending on a rejected claim. Concerning claims 10,11,19-22,24 & 25 there is no prior art that teach or suggest the method by further adding at least positive controls to the test column where the positive control snare is separated spatially by an intervening air space. Concerning claims 12,13 & 23 there is no prior art that teach or suggest the method further comprising adding negative control where the negative control snare is spatially separate from other snares by an intervening air space or a blank snare separated spatially by an intervening air space. Wainwright et al (US5,876,918) teach a column like device but do not teach or suggest detecting multiple analytes in test sample or snares are separated by an intervening air space. Urnovitz et al teach detecting multiple antigens on a test strip that are bound to discrete areas but they do not teach or suggest a column the strips are placed in wells.

CONCLUSION

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number before January 22, 2003 is (703) 305-3886 and thereafter can be reached at 571-272-0787. The e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the

examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703)-305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and FAX (703)-308-4242.

JEFFREY SIEW
PRIMARY EXAMINER

February 8, 2004